

## **REMARKS**

### **I. Introduction**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-20, 23, 25, 31-40 and 43-45 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 21 and 28 are currently being amended. The amendments to claims 21 and 28 clarify what Applicants regard as the invention.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

The claims, as amended, are directed to SEQ ID NO: 3. Exemplary support for the claim amendments is found throughout the specification. For example, exemplary support for the amendment to claim 21 is found in the specification on page 21, line 10.

Upon entry of this Amendment, claims 21, 22, 24, 27-30, 41 and 42 are pending, with claims 24, 29, 30, 41, 42 withdrawn from consideration, and claims 21, 22, 27, and 28 ready to be examined on the merits.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

### **II. Response to Issues Raised by Examiner in Outstanding Office Action**

#### **a. Interview of August 8, 2004**

Applicants would like to thank Examiner Harris for her time and insights during a telephonic interview with Applicants' representative on August 8, 2004.

**b. Claim Rejections - 35 U.S.C. § 112, First Paragraph (Alleged Lack of Enablement)**

Claims 21, 27, 28 and 43-45 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph for alleged lack of enablement. The Examiner asserts that a person of ordinary skill in the art would be forced into undue experimentation in order to practice the broadly claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants have canceled claims 43-45, thus rendering the rejection of these claims moot. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

**i. The specification provides sufficient guidance to enable a person of ordinary skill in the art to make and use the claimed polypeptides**

With respect to claims 21, 22, 27 and 28, a person of ordinary skill in the art, using techniques well known in the art as well as the teachings of the specification, would be able to make the claimed polypeptides without undue experimentation. Firstly, Applicants have deleted the term “naturally occurring” from claim 21(b) and have amended claim 21(b) to recite “a polypeptide comprising a sequence having at least 95% sequence identity SEQ ID NO: 3, said polypeptide having apoptotic activity.” As SEQ ID NO: 3 comprises 238 amino acids, a polypeptide comprising a sequence having at least 95% sequence identity SEQ ID NO: 3, would have up to only 12 amino acid variations as compared to SEQ ID NO: 3.

Secondly, page 19 of the specification identifies the location of four potential casein kinase II phosphorylation sites and four protein kinase C phosphorylation sites. Page 19 of the specification also identifies a region from amino acid 31 to amino acid 40 of SEQ ID NO: 3 that has been identified in various libraries, many of which are associated with proliferating or cancerous tissue or an immune response. A person of ordinary skill in the art would know to maintain these regions in order to maintain the necessary activity and function.

Finally, a person of ordinary skill in the art would know how to use the claimed polypeptides. As described above, page 19 of the specification identifies the location of four

potential casein kinase II phosphorylation sites and four protein kinase C phosphorylation sites. Page 19 of the specification also identifies a region from amino acid 31 to amino acid 40 of SEQ ID NO: 3 that has been identified in various libraries, many of which are associated with proliferating or cancerous tissue or an immune response. Pages 32 and 43 disclose diseases associated with increased or decreased apoptosis for which the claimed invention can be used to treat or diagnose.

For the reasons discussed above, a person of ordinary skill in the art would know how to make and used the polypeptides of the claimed invention.

**c. Claim Rejections - 35 U.S.C. § 112, First Paragraph (Alleged Lack of Written Description)**

Claims 21, 22, 27, 28 and 43-45 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for alleged lack of written description. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants have canceled claims 43-45, thus rendering the rejection of these claims moot. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

The Examiner asserts that the genus of polypeptides denoted as naturally-occurring having at least 90% sequence identity to the sequences of SEQ ID NO: 3 and 5, biologically active and immunogenic, comprises undefined sequences encompassing a variety of subgenera with widely varying attributes. The Examiner asserts that it is essential that there is a functional and structural correlation which defines the species. Applicants have deleted the term “naturally occurring” from claim 21(b) and have amended claim 21(b) to recite “a polypeptide comprising a sequence having at least 95% sequence identity SEQ ID NO: 3, said polypeptide having apoptotic activity.” The claims also recite that the polypeptide has apoptotic activity. These recitations are supported by the specification, for example, on page 4, lines 6-18, as well as on page 19. Therefore, sufficient function and structure is provided for the claimed invention.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

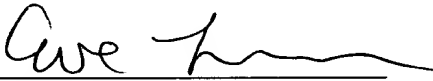
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

October 12, 2004  
Date

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